

# Notice of Allowability

Application No.

09/955,485

Examiner

Phyllis G. Spivack

Applicant(s)

MOSKOWITZ ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed February 18, 2004.
2. ☒ The allowed claim(s) is/are 21, 22, 24-28, now renumbered 1-7.
3. ☒ The drawings filed on 19 September 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☒ None of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 3-15-04
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Phyllis G. Spivack  
Primary Examiner  
Art Unit: 1614

#### EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On page 18, line 16, of the specification, "No-" is deleted and --- NO- -- is inserted therefor.

Authorization for this examiner's amendment was given in a telephone interview with Danielle Herritt on June 7, 2004.

The following is an Examiner's statement of Reasons for Allowance:

An Amendment filed February 18, 2004 is acknowledged. Claims 1-20, 23 and 29-35 are canceled. Claims 21, 22 and 24-28 remain under consideration.

An Information Disclosure Statement filed March 15, 2004 is further acknowledged and has been reviewed.

Claims 20, 21, 23, 24 and 28 were rejected under 35 U.S.C. 103 as being unpatentable over Myslivecek et al., Neuroscience, in the last Office Action. It was asserted Myslivecek teaches the substantially contemporaneous administration of the NO-increasing agent, L-arginine, with a physiologically active dopamine composition, in the brain.

Applicants have amended the claims such that only a simvastatin composition is recited as the physiologically active composition. Accordingly, the rejection of record under 35 U.S.C. 103 is withdrawn.

Two other rejections of record of claims 29-35 under 35 U.S.C. 103 are moot following the cancellation of the claims.

Claims 20-28 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as not providing enablement for increased bioavailability of any physiologically active composition.

Following the amendments to independent claims 21 and 22, wherein the claims were limited to simvastatin compositions, the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

The prior art does not teach or suggest a method of increasing cerebral bioavailability specifically of a simvastatin composition comprising introducing the composition into the blood stream substantially contemporaneously with either L-arginine and/or another NO-increasing agents. NO-increasing agents are well known in the prior art. Pages 13-14 of the specification recite numerous examples. Thus claims 21, 22 and 24-28 are allowed in view of the contemporary knowledge of the art.

Any comments considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.



Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614

**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**

June 7, 2004